

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SIGHT SCIENCES, INC.,)	
)	C. A. No.: 21-1317-GBW-SRF
Plaintiff,)	
)	JURY TRIAL DEMANDED
v.)	
)	
IVANTIS, INC., ALCON RESEARCH LLC,)	
ALCON VISION, LLC AND ALCON INC.,)	
)	
Defendants.)	

**PLAINTIFF SIGHT SCIENCES, INC.'S RESPONSE
TO DEFENDANTS' OBJECTIONS TO MAGISTRATE JUDGE FALLON'S
REPORT AND RECOMMENDATION REGARDING CLAIM CONSTRUCTION**

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I. INTRODUCTION

Defendants’ Objections (D.I. 139, hereinafter “Obj.”) rehash arguments that the Report and Recommendation (D.I. 134, hereinafter “R&R”) correctly rejected in view of the intrinsic record and well-established doctrines of claim construction. First, Defendants’ litigation-driven attempt to narrow “support” from its plain and ordinary meaning ignores the intrinsic evidence on which the R&R relied, and fails to establish a *clear and unmistakable* disavowal of claim scope. Second, Defendants ignore their evidentiary burden of establishing by *clear and convincing evidence* that the “substantial interference,” “30% of C,” and “radius of curvature” limitations are indefinite. The R&R’s reasoning and conclusions are sound, and as such, Plaintiff Sight Sciences, Inc. (“Sight”) respectfully requests that the Court adopt the R&R’s constructions.

II. ARGUMENT

A. The R&R Correctly Construed “Support”

Defendants have never disputed that the plain and ordinary meaning of “support” is “a structure that props something open,” i.e., “a prop.” Instead, they object to the R&R’s construction in an attempt to drastically limit the scope of *every claim* of the Asserted Patents to supports that “do not occupy at least a portion of the central core of Schlemm’s canal.” Under *Phillips* and its progeny, discarding a term’s plain and ordinary meaning is only appropriate in two circumstances: where the patentee has acted as his own lexicographer, and where there has been a “clear and unmistakable” disavowal of the full scope of a term’s meaning. *GE Lighting Sols., LLC v. Agilight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2014). Defendants do not allege lexicography, but rather argue that patentees disavowed supports that do not occupy at least a portion of the central core of Schlemm’s canal—an assertion refuted by the intrinsic record and correctly rejected by the R&R.

Defendants fixate on the Asserted Patents’ various descriptions of preferred embodiment supports that occupy at least a portion of the central core of Schlemm’s canal. (*See* Obj. at 1-2.)

But as recounted in the R&R and discussed below, the Asserted Patents *expressly contemplate* embodiments of the claimed supports that do *not* occupy at least a portion of the central core of Schlemm’s canal. (See R&R at 10-13.) Defendants inexplicably ignore these teachings.

First, Defendants argue that the R&R erred by not finding the Asserted Patents’ purported “disparagement” of “hollow tubular supports” (which would not occupy at least a portion of the central core of Schlemm’s canal) to rise to the level of disavowal. (Obj. at 3 (citing R&R at 10).) Defendants list the patents’ criticisms of *some* prior art hollow tubular supports, but notably omit from their quotations the very language supporting the R&R’s conclusion: The patents make clear that hollow tubular supports “*can be*” prone to certain problems, informing a person of skill in the art that “these drawbacks do not arise every time an open-ended tubular support is used.” (R&R at 10 (citing D.I. 119, Ex. 1 at 2:29-47, 7:63-67).) Such permissive language does not amount to disavowal. See *Thorner v. Sony Comput. Ent. Am. LLC*, 669 F.3d 1362, 1366-67 (Fed. Cir. 2012).

Second, Defendants suggest that the R&R erred by applying an “impossible to achieve” standard for disparagement to amount to disavowal. (Obj. at 3 (citing R&R at 11).) But that was not the standard the R&R applied. The R&R’s rejection of disavowal was instead grounded in the *multiple, express disclosures* in the Asserted Patents confirming “open-ended tubular supports fall within the scope of the invention.” (R&R at 10.) First, the R&R cited the disclosure of structural features for improving transmural and longitudinal flow that would address shortcomings in prior art designs without occupying at least a portion of the central core of Schlemm’s canal. For example, the patents describe “adding fluted edges or fenestrations to reduce surface area contact with the canal walls and using permeable materials such as mesh.” (R&R at 10 (citing D.I. 119, Ex. 1 at 3:47-51, 9:21-28, 11:5-7).) Second, the R&R cited the Asserted Patents’ teachings that the “devices described here *need not comprise an open-ended tubular support* placed

longitudinally along Schlemm’s canal, i.e., the devices and supports *can be* non-tubular.” (R&R at 10 (quoting D.I. 119, Ex. 1 at 7:48-50) (emphasis added).) Such teachings inform an ordinarily skilled artisan that the claimed invention *could be* carried out using an open-ended tubular support. Crucially, there is *no dispute* that an “open-ended tubular support” would not occupy the central core of Schlemm’s canal. These disclosures alone support the R&R’s construction.

Third, Defendants accuse the R&R of “imagining” modifications to element 95 in Figures 6A/6B. (Obj. at 4 (citing R&R at 12-13).) But the R&R did not imagine modifications; it applied express teachings that the elements depicted in Figures 6A and 6B “may be hollow and closed structures, open structures, solid structures, porous structures, *or any combination thereof*, and may be of any suitable shape.” (R&R at 11 (quoting D.I. 119, Ex. 1 at 9:25-28) (emphasis added).) Defendants’ Objections fail to mention, let alone address this disclosure. The R&R also rightly dismissed Defendants’ evidence-free assertion at the claim construction hearing that a “hollow and open” version of element 95 *must* have “thick walls ... such that the support still occupies at least a portion of the central core of the canal.” (R&R at 12-13 (citing 2/9/2023 Hearing Tr. at 32:18-33:6).) The specification imposes no such dimensional restrictions. These disclosures alone also substantiate the R&R’s conclusions, and as such, Patentees did not clearly disavow supports that do not occupy a portion of the central core of Schlemm’s canal. (*See* R&R at 13.)

Finally, Defendants criticize the R&R’s proper reliance on the doctrine of claim differentiation. But the R&R did not rely on claim differentiation to “broaden claims beyond their meaning in light of the specification,” as Defendants accuse. (Obj. at 4 (quoting *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1302 (Fed. Cir. 1999)).) Instead, given the foregoing intrinsic evidence, the R&R concluded correctly that the “particularly strong” presumption of claim differentiation is not overcome in the circumstances presented here. (R&R at 13 (citing *SunRace*

Roots Enter. Co. v. SRAM Corp., 336 F.3d 1298, 1302-03 (Fed. Cir. 2003)).) The patents' differentiated claims confirm the specification, which recognizes that supports *need not* occupy a central core of Schlemm's canal. The R&R should be adopted because it follows the law, correctly honors the intrinsic evidence, and adopts the agreed-upon plain and ordinary meaning of "support."

B. The "Substantial Interference" Limitation is Not Indefinite

The burden for proving indefiniteness is an exacting one: clear and convincing evidence. *See Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901, 912 n.10 (2014). The record, as thoroughly set forth by the R&R, confirms that Defendants failed to meet their burden. To the contrary, the evidence established that a POSA would encounter no difficulties ascertaining the scope of the "substantial interference" limitations with reasonable certainty.

Each of Defendants' disputes with the R&R's construction is meritless. First, Defendants argue that the R&R's construction merely swaps one indefinite term for another, and that "neither Plaintiff nor the R&R points to examples of, or ways to distinguish" supports that substantially interfere from those that do not. (Obj. at 4-5.) But as is typical throughout their objections, Defendants simply ignore the intrinsic and extrinsic evidence contradicting their position, much of which is undisputed. There is no dispute, for example, that the express object of the inventions claimed by the Asserted Patents is to restore the eye's natural drainage network and reduce intraocular pressure ("IOP"). (D.I. 119, Ex. 1 at 6:14-21.) There is no dispute that the Asserted Patents disclose ranges of aqueous outflow and IOP that can be achieved using the supports. (*See* R&R at 23-24 (citing D.I. 119, Ex. 1 at 7:39-42).) There is no dispute that a POSA would be able to experimentally measure the effect that a support would have on both the rate of aqueous outflow and IOP. (D.I. 120, Ex. 34 at 163:13-21, 164:19-165:3, 165:20-166:7, 168:5-14, 169:5-21, 170:21-171:14.) Nor is there a dispute that the rate of aqueous outflow and IOP are directly correlated with one another through a mathematical relationship known as the Goldmann equation. (D.I.

120, Ex. 34 at 162:1-8; D.I. 119, Ex. 20 at 133:24-134:7.) As Plaintiff’s expert testified, in view of this undisputed evidence, a POSA would evaluate whether a support “substantially interferes” or “significantly blocks” fluid flow in the eye by determining whether an increase in aqueous outflow (and therefore a decrease in IOP) has been achieved by the support. (See R&R at 23 (citing D.I. 119, Ex. 19 ¶¶ 23-24).) Therefore, contrary to Defendants’ assertions, the Asserted Patents disclose clear, objective criteria (aqueous outflow and IOP) by which a POSA could readily determine whether a support substantially interferes with fluid flow in the eye.

Equally incorrect is Defendants’ assertion that “neither Plaintiff nor the R&R points to examples of ... supports that ‘substantially interfere’” (Obj. at 5.) Sight’s briefing as well as the R&R discussed such examples at length. (See R&R at 23 (citing D.I. 119, Ex. 1 at 2:41-47, Fig. 5B, 5:21-23, 8:54-63); D.I. 118 at 20.) The Asserted Patents disclose clear, objective criteria by which a POSA could determine whether a support substantially interferes with fluid flow in the eye, and provide examples of supports that do or do not meet those criteria. (*Id.*) As such, this case is analogous to *Enzo*, *Exmark*, and *Sonix* where claim limitations were found not indefinite, and readily distinguishable from *Huber* and *Clear Imaging Research*. (See Obj. at 5-6.)

Second, Defendants accuse the R&R of “effectively rewrit[ing] the claims, requiring only net changes to outflow or intraocular pressure” (Obj. at 5 (citing R&R at 23-24).) Here, Defendants ignore that “[c]laim language, standing alone, is not the correct standard of law” in an indefiniteness analysis, but rather the claims must be “viewed and understood in light of the specification” *Nature Simulation Sys. Inc. v. Autodesk, Inc.*, 50 F.4th 1358, 1364 (Fed. Cir. 2022) (en banc) (internal quotation marks and citation omitted). Defendants not only failed to establish by clear and convincing evidence that a POSA would not understand the scope of the claim with reasonable certainty, but both parties’ experts also agreed that measurement of a net

substantial blocking effect was possible: Sight’s expert testified that a POSA would be reasonably certain as to the scope of the “substantial interference” claim limitation precisely because the *specifications* provide clear, objective criteria (aqueous outflow and IOP) by which the question of whether or not a support “substantially interfered” with fluid flow could be ascertained. (*See* R&R at 23 (citing D.I. 119, Ex. 19 ¶¶ 23-24).) And Defendants’ expert conceded that “net substantial blocking effect” could be measured and determined. (D.I. 120, Ex. 34 at 163:13-21.)

Finally, Defendants advance two new arguments that never appeared in the parties’ briefing. First, Defendants contend that “[t]he R&R’s construction collapses [longitudinal and transmural flow] into one,” thereby rendering ’443 claim 56 “invalid under the R&R’s construction” (Obj. at 6.) Defendants’ failure to raise this argument timely is particularly notable given the R&R adopted the very construction Sight proposed in its *opening* claim construction brief. (*See* D.I. 118 at 19.) Defendants also argue for the first time that a POSA would be unable to discern “whether a support substantially interferes with longitudinal flow or transmural flow ...” by measuring IOP and aqueous outflow. (Obj. at 7.) Defendants waived these untimely arguments by failing to set them forth in the parties’ Joint Claim Construction Brief. *See Persawvere, Inc. v. Milwaukee Elec. Tool Corp.*, C.A. No. 21-400-GBW, 2023 WL 2140033, at *5 (D. Del. Feb. 21, 2023). But even if the Court were to consider these arguments, they are meritless. The testimony of Sight’s expert—which was credited by the R&R—confirms that a POSA would be able to distinguish substantial interference with longitudinal *or* transmural flow based on the design and surface area contact of the support, in view of the teachings of the Asserted Patents. (*See* R&R at 23-24; D.I. 119, Ex. 1 at Fig. 5B, 2:30-33, 2:40-47, 7:51-52, 7:63-67, 8:54-63.)

The R&R should be adopted because Defendants fail to show by clear and convincing evidence that the “substantial interference” limitation is indefinite, that the R&R’s fact findings

are clearly erroneous, or that its conclusions are contrary to law.

C. The “30% of C” Limitation is Not Indefinite

A POSA would have no difficulty ascertaining the meaning and scope of the “30% of C” limitation with reasonable certainty. (*See* R&R at 27-29.)

First, the “30% of C” limitation expressly refers to an *estimate* of surface area contact, and not *actual* surface area contact as Defendants incorrectly assert. (*See* Obj. at 7.) As the R&R recognized, and as is undisputed by the parties, the term “C” is not one that has a plain and ordinary meaning—it is one defined by the specification. (*See* R&R at 26-27 (citing D.I. 119, Ex. 1 at 11:16-20; *id.*, Ex. 20 at 120:13-17).) As such, the patents’ explicit definition of “C” is controlling. *See Jack Guttman, Inc. v. Kopykake Enters., Inc.*, 302 F.3d 1352, 1360-61 (Fed. Cir. 2002) (“Where, as here, the patentee has clearly defined a claim term, that definition usually is dispositive; it is the single best guide to the meaning of a disputed term.” (cleaned up)); *see also, e.g., Baxalta Inc. v. Bayer HealthCare LLC*, C.A. No. 1:17-cv-1316-RGA, 2019 WL 3290987, at *3 (D. Del. July 22, 2019). Moreover, there is no dispute that a POSA would have considered measuring actual surface area contact to be essentially impossible; in suggesting that the “30% of C” limitation nevertheless requires such a calculation, Defendants ignore that the point of the patents’ disclosure is to define how to *estimate* internal wall surface area. (*See* D.I. 119, Ex. 19 ¶¶ 28-29; *id.*, Ex. 20 at 36:8-16, 44:17-20, 46:21-47:4, 49:23-50:4, 55:1-5, 62:16-63:6.)

Defendants attempt to downplay the significance of the explicit definition of “C” by recasting it as an “exemplary embodiment” (Obj. at 8), but this characterization is plainly mistaken. The fact that definitional language is *applied* to an exemplary embodiment (in Figures 9A and 9B) does not render the definition itself exemplary, where, as here, the claims expressly invoke “C.”

Second, Defendants’ throwaway argument that the R&R’s construction “is silent ... as to how the estimate is applied to a non-cylindrical support” is incorrect. (Obj. at 8.) The R&R

rightfully credited the testimony of Sight's expert Dr. Downs showing that "a person of ordinary skill would understand how to determine the size of the cylinder, the contact points, and the length of the support to perform a surface area calculation based on the guidance in the specification." (R&R at 28-29 (citing D.I. 119, Ex. 20 at 69:14-24, 72:17-21, 75:14-16, 111:6-15).) Nor is there any ambiguity about how to measure the surface area of a "slightly arcuate" cylinder as Defendants allege—Defendants' expert testified that he could do so "pretty easily," as could any POSA. (D.I. 120, Ex. 34 at 123:24-124:5, 124:17-20; *see also* D.I. 119, Ex. 20 at 64:14-17, 80:25-81:9.)

Third, nothing in the prosecution history contradicts the patents' explicit definition of "C." Finding no support in the specification for their contention that the claims require measuring actual contact, Defendants resort to a tortured interpretation of a statement made during prosecution of the '482 patent in reference to the *Examiner's* characterization of prior art (Shadduck). Defendants' reliance on this statement is misplaced. As the R&R recognized, the patentee simply observed that Shadduck "did not make *any* disclosure about the amount of contact, either actual or estimated, between the apparatus and the surrounding tissue." (R&R at 28 (citing D.I. 120, Ex. 35 at 14-15) (emphasis added).) And even if Defendants' characterization of the prosecution history were accurate, Defendants cite no authority suggesting that such a statement could somehow nullify the clear, definitional language set forth in the specification.

Finally, Defendants attempt to fault the R&R for "citing Defendants' patent application related to the accused product as evidence that a hypothetical cylinder can be used to estimate surface area contact." (Obj. at 9.) Defendants misstate the R&R. (*See* R&R at 29 ("But the court need not consider evidence regarding Defendants' own product").) It nevertheless would have been proper for the R&R to consider Defendants' own proven ability to calculate the amount of contact between a support and a hypothetical cylinder surrounding that support, as such evidence

weighs against a finding of indefiniteness. *See Liqwd, Inc. v. L'Oréal USA, Inc.*, 720 F. App'x 623, 631 (Fed. Cir. 2018) (citing *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1368 (Fed. Cir. 2017)); (D.I. 118 at 42-43 (citing D.I. 119, Ex. 37 at [000111])). The R&R should be adopted. Defendants fail to show by clear and convincing evidence that the “30% of C” limitation is indefinite, or that the R&R’s findings are clearly erroneous or its conclusions are contrary to law.

D. The “Radius of Curvature” Limitation is Not Indefinite

A POSA would have no difficulty ascertaining the meaning and scope of the “radius of curvature” limitation with reasonable certainty. (*See* R&R at 29-34.) Record evidence shows that Defendants have been able to do precisely what the claims require: (1) ascertain the radius of curvature of a portion of an arcuate support, and (2) compare that radius of curvature with the radius of curvature of Schlemm’s canal. (*See* D.I. 119, Ex. 16, IVANTIS_SS_00001276 at 1280-81.) This evidence is properly considered in rebutting allegations of indefiniteness. *See Liqwd*, 720 F. App'x at 631 (citing *BASF*, 875 F.3d at 1368 and *Sonix Tech. Co. v. Publ'ns Int'l, Ltd.*, 844 F.3d 1370, 1379-80 (Fed. Cir. 2017)).

There is no ambiguity about how to measure the radius of curvature (“ROC”) of a portion of an arcuate member, and *Saso Golf* is distinguishable. (*See* R&R at 33; D.I. 118 at 73; 2/9/23 Hearing Tr. at 117:2-17.) Both parties’ experts agree that an arc is a segment of a circle that, by definition, has a radius of curvature. (D.I. 119, Ex. 20 at 177:20-179:11; D.I. 120, Ex. 34 at 66:16-67:4, 67:9-13.) The start and end of each arc is thus geometrically defined by a constant radius of curvature. (D.I. 119, Ex. 20 at 178:21-179:25; R&R at 33 (“[T]he specification illustrates the portions of an arcuate member having a radius of curvature as portions of a perfect circle.”).) Therefore, a POSA would know with reasonable certainty from where to determine the ROC of a portion of an arcuate member. Defendants’ new observation that “the asserted patents are not limited to ‘perfect circles’” is beside the point, because the “complex shapes in Figs. 6A-B [and]

8A-H,” (Obj. at 10), are *not arcuate members*. (See R&R at 18-19 (“Not every support described in the specification comprises an arcuate member”))

Defendants also quibble with alleged differences that theoretically might arise if the ROC is measured from the “innermost edge or the outermost edge” of a three-dimensional support. (Obj. at 10.) This argument, which is devoid of evidentiary support, was raised for the first time at the claim construction hearing (see 2/9/23 Hearing Tr. at 112:25-113:14) and is thus waived. *Persawvere*, 2023 WL 2140033, at *4-5. In any event, because the *width* of a support in Schlemm’s canal and *the ROC* of Schlemm’s canal are separated by multiple orders of magnitude, the resulting difference in measurement would be essentially a rounding error. (Compare D.I. 119, Ex. 1 at 8:65-9:8 (describing support widths of “about 50 microns to about 500 microns ...”), with *id.*, Ex. 19 ¶ 40 (noting Schlemm’s canal has an ROC of about 6 mm).) “Mathematical precision” is not the standard for definiteness. *Sonix*, 844 F.3d at 1377 (quoting *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 424 F.3d 1374, 1384 (Fed. Cir. 2005)).

Defendants’ attempt at the hearing to manufacture confusion about the ROC of Schlemm’s canal based on purported differences in the labeling of “Rsc” across Figures 11A-11C was also never raised in the briefing and is equally bereft of evidentiary support. (See Obj. at 9-10.) Both parties’ experts testified that a POSA would be familiar with the ROC of Schlemm’s canal, which was commonly understood by skilled artisans to be about 6 mm. (See D.I. 119, Ex. 20 at 196:22-25; D.I. 120, Ex. 34 at 59:18-60:2.) Because a POSA would have no difficulties ascertaining: (1) the ROC of a portion of an arcuate member, and (2) the ROC of Schlemm’s canal, Defendants have not shown by clear and convincing evidence that this term is indefinite, that the R&R’s fact findings are clearly erroneous, or that its conclusions are contrary to law.

III. CONCLUSION

Based on the foregoing, the claim constructions set forth in the R&R should be adopted.

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